

Remarks

The non-final Office Action dated September 11, 2008 has been reviewed and following remarks are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Claims 1-23 are pending.

Rejections under 35 U.S.C. 102

Claims 1-9 were rejected under 35 U.S.C. 102(b) as being anticipated by Imondi *et al.* (U.S. Patent No. 4,143,130) ("*Imondi*"). In particular, the Examiner alleged that *Imondi* discloses a method for the treatment of kidney diseases comprising administering swellable polymers to a patient in enterically coated oral formulations and compositions comprising said polymers and are capable of absorbing physiological saline (Office Action at page 2). Applicants respectfully traverse this rejection.

Applicants respectfully point out that *Imondi* is directed to methods for treating kidney stones, not kidney disease as suggested by the Examiner, whereas the instant claims are directed toward a method for increasing fluid loss through the feces. Notably, the polymers of *Imondi* bind calcium and thus would poorly absorb fluid. Given that *Imondi* fails to expressly or inherently disclose increasing fluid loss through the feces, *Imondi* cannot anticipate the instant claims. Accordingly, Applicants respectfully request that the rejection of claims 1-9 under 35 U.S.C. 102(b) be reconsidered and withdrawn.

Claims 1-2 and 4-9 were rejected under 35 U.S.C. 102(b) as being anticipated by Motoki Yonekawa *et al.* (JP H10-130154) ("*Yonekawa*"). In particular, the Examiner alleged that *Yonekawa* discloses a method of oral administration of drug comprising acrylic type water absorbent monomer as an active component that is capable of absorbing 5 to 100X its weight in a physiological saline solution (Office Action at page 3). Applicants respectfully traverse this rejection.

Applicants submit that *Yonekawa* does not provide for direct delivery of a water-absorbent polymer to the intestinal tract. The Examiner mistakenly suggests that administering a hard gelatin capsule would prevent the polymer from being exposed to the stomach prior to delivery to the GI tract (Office Action at page 3). Applicants respectfully point out that gelatin capsules typically dissolve within minutes in the stomach and release their contents in the stomach. In contrast, an enteric coat dissolves in the intestinal tract. Given that *Yonekawa's*

does not provide for direct delivery of its polymer to the intestinal tract, *Yonekawa* cannot anticipate the instant claims. Accordingly, Applicants respectfully request that the rejection of claims 1-2 and 4-9 under 35 U.S.C. 102(b) be reconsidered and withdrawn.

Rejections under 35 U.S.C. 103

Claims 1, 4-6, 9, 13 and 15-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Berger et al.* (U.S. Patent No. 4,470,975) ("*Berger*"). In particular, the Examiner alleged that it would have been obvious to one of skill in the art at the time of the invention to generate a method for increasing fluid loss through the feces in a host comprising the step of directly administering to the intestinal tract of the host an effective amount of a water-absorbent polymer for increasing the fluid in the feces (Office Action at page 5). Applicants respectfully traverse this rejection.

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (citing *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (US 2007))). "Subsumed within the Graham factors is a subsidiary requirement articulated by this court that where, as here, all claim limitations are found in a number of prior art references, the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). As such, a finding of obviousness at least requires that the all of the claim elements be taught or suggested in the cited art.

Applicants respectfully submit that *Berger* does not provide or suggest directly administering a water-absorbent polymer to the intestinal tract to increase fluid loss through the feces. Instead, the polymers of *Berger* are orally administered (e.g., mixed with food or mineral oil) and are subsequently exposed to the stomach contents (e.g., gastric juices). In contrast, the water-absorbent polymers of the instant invention are directly administered to the intestine. The

Examiner appears to infer that directly administering the polymer of *Berger* to the intestinal tract would have been obvious to a skilled artisan to increase fluid loss through the feces. However, such a conclusion can not be drawn from *Berger*. Notably, the Examiner has failed to set forth any motivation as to why one of skill in the art would modify the polymers of *Berger* to increase fluid loss through the feces if the polymers of *Berger* already possessed this property as alleged by Examiner. Given that *Berger* does not teach or suggest every element of the instant claims it cannot render the instant claims obvious. Accordingly, Applicants respectfully request that the rejection of claims 1, 4-6, 9, 13 and 15-17 under 35 U.S.C. 103(a) be reconsidered and withdrawn.

Claims 1-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Yonekawa* or *Imondi* in view of *Berger*. In particular, the Examiner asserts that it would have been obvious at the time of the invention to use the combination of cellulosic polymers and the composition in the form of enteric coated tablet or capsule for treatment of excess fluid in the gastrointestinal tract as taught by *Imondi* and *Yonekawa* (Office Action at page 6). Applicants respectfully traverse the rejection.

Applicants respectfully request clarification concerning the references cited by the Examiner in this rejection. The claims were rejected as being unpatentable over *Yonekawa* or *Imondi* in view of *Berger*, however, *Tsuji* (U.S. Patent No. 4,670,287) ("*Tsuji*") not *Berger* is used by the Examiner in combination with *Yonekawa* or *Imondi*. Applicants arguments below are based on the assumption that the caption of the rejection mistakenly stated *Berger* instead of *Tsuji*.

As discussed above, *Imondi* and *Yonekawa* fail to expressly or inherently provide each and every element of the claimed invention. Applicants submit that *Tsuji* fails to remedy the defects of *Imondi* and *Yonekawa*. The Examiner relies on *Tsuji* for the disclosure of enterically coated hard capsules and alleges that a skilled artisan would have been motivated to use the enteric coatings of *Tsuji* with the polymers of *Imondi* and *Yonekawa* to arrive at the instant invention. Applicants submit that *Imondi* and *Yonekawa* taken singly or in combination with *Tsuji* fail to provide or suggest direct delivery of a water-absorbent polymer to the intestinal tract to increase fluid loss through the feces and even in combined would not yield the claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 1-2 and 4-9 under 35 U.S.C. 103(a) be reconsidered and withdrawn.

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Conclusion

Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting prosecution of this application. The Commissioner is authorized to charge any underpayment of fees or credit any overpayment of fees to Deposit Account No. 02-1818 (order no. 117878-11) for any matter in connection with this response.

Respectfully submitted,
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